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PD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/648,270 05/15/96 TOR

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EXAMINER

CRANE, L

ART UNIT:

PAPER NUMBER

1623

25

DATE MAILED:

10/18/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/648,270

Applicant(s)

Tor et al.

Examiner

L. E. Crane

Group Art Unit

1623

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 09/21/99 (CPA and Amdt E)
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 26-47 is/are pending in the application.
- Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 26-47 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.
- [x] Claims 1-25 have been cancelled.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s): _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

5 The instant file wrapper contains a page following the claims with the printed heading "ABSTRACT," but the page is otherwise blank. Examiner respectfully requests that applicant submit by amendment an appropriate abstract for insertion on the noted page.

10 Claims 1-25 have been cancelled and new claims 26-43 and 44-47 have been added as per amendments including those filed December 23, 1998 and September 21, 1999.

Claims 26-47 remain in the case.

15 Claims 26-47 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 In claim 26, line 8, the term "acetene" is technically incorrect. Additionally the remaining terms are either technically incorrect or unclear as to their intended meaning in context (e.g. "acetylene" is a compound, not a diradical linking moiety). Did applicant intend the noted line to read

-- from the group consisting of $-C\equiv C-$, $-CH=CH-$, $-N=N-$ and $-CH=N-$ -- ? A similar problem occurs in claims 44-46 which may be effectively addressed in a similar manner; e.g. the term
25 "acetylene" may be replaced by the term -- $-C\equiv C-$ --.

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Applicant's arguments with respect to claim 26 has been considered but are moot in view of the new grounds of rejection.

In claim 26, line 9, the term "X and X₁ are co-ligands and wherein at least one of X and X₁ is present." is indefinite because the chemical identities of the noted "ligands" is not further defined (Markush group in the specification?) in the instant claim in chemical terms thereby rendering the scope of the instant claim indefinite. This same problem reoccurs in claim 27.

Applicant's arguments filed September 21, 1999 have been fully considered but they are not persuasive.

Applicant argues that the meaning of "ligand" is well known to one of skill in the art. Examiner agrees but considers this argument beside the point. The instant claim's definitions of "X" and "X₁" are not sufficiently well defined to permit the ordinary practitioner to know which ligands are to be included and which ligands are not to be included within the metes and bounds of the instant claim. This is an invitation to try (or to guess), as opposed to the desired definition of applicant's contribution to the art.

In claim 26, line 19, the Markush groups are improperly formulated; the term "or" occurs twice in the noted line. The proper Markush group formulation is as follows: -- selected from the group consisting of [A], [B], ... **and** [R] -- (emphasis added). The same problem reoccurs in claim 27.

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Applicant's arguments with respect to claim(s) **26-27** have been considered but are moot in view of the new grounds of rejection.

In claim **28**, line 3, the term "substitution group" is incorrect. Did applicant intend the term to read -- substituent group -- ?

5 This problem reoccurs in claims **29, 32, 35, 38 and 41-42**.

Applicant's arguments with respect to claim(s) **28-29, 32, 35, 38 and 41-42** have been considered but are moot in view of the new grounds of rejection.

10 Applicant's cancellation of claims directed to non-elected subject matter is noted with appreciation. However, inspection of claims **26-43**, particularly claims **26, 27, 28** (a carbohydrate moiety) **and 41-42**, reveals that said claims are in part, or in their entirety, directed to subject matter which is non-elected. Applicant is respectfully requested to adhere in the instant claims to the subject
15 matter elected in Paper No. **9** (Group **V**).

Applicant's arguments with respect to claim(s) **26-43** have been considered but are moot in view of the new grounds of rejection.

20 In claim **26 and 27**, subsections "c)" and "d)", the term "substituted aromatic group" lacks an upper bound (no maximum size defined) and therefore renders the instant claims lacking in adequately defined metes and bounds.

Applicant's arguments with respect to claim(s) **26-27** have been considered but are moot in view of the new grounds of rejection.

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In claims 26-47 the subject matter of the instant claims is indefinite because the attachment point or attachment points of the "Z" substituent have not been defined.

Applicant's arguments with respect to claim(s) 26-43 have been considered but are moot in view of the new grounds of rejection.

Claims 26-47 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 26-47 the subject matter is directed to a vast array of substituent moieties but applicant's disclosure is limited in its specific embodiments to substituted nucleosides, substituted nucleotides, and substituted nucleoside phosphoramidites and nucleic acid sequences including a substituted nucleoside. For example in claim 26, line 5, the term "M is a transition metal ion" is lacking in enabling support within the instant disclosure in the form of any showing that applicant had possession of compounds of the kind indicated, that a substantial number of transition metal complexes had actually been made, and that the method of making described in sufficient detail to permit the ordinary practitioner to know how to make said compounds based on contents of the instant disclosure. Previous policy guidance on enablement to the effect that the "law requires that disclosure in an application shall inform those skilled in the art how to use appellant's alleged discovery, not how to find out how to use it for themselves" (*In re Gardner et al.*, 166 USPQ 138 (CCPA 1970)), has apparently become the judicial policy of the

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5 successor (CAFC) court. Examiner refers applicant to the recent April, 1999 ABA meeting in Washington, DC and the Program Book therefrom wherein numerous appellate practitioners reported that claims lacking proper enabling support were being dispatched by that court to the circular file via findings of invalidity, a policy which the practitioners promised is in the process of being extended by the CAFC to all subject matter areas. Therefore, examiner respectfully suggests that the instant claims be redrafted with this policy in mind, and that additional data if available be added in CIP filings as appropriate to support claims drafted to include presently non-enabled subject matter.

10 Applicant's arguments with respect to claim(s) 26-43 have been considered but are moot in view of the new grounds of rejection.

15 Claim(s) 26-47 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20 Claims 26-47 are broadly descriptive of the claimed invention, but the specific embodiments teach with a very small number of example how the instant invention may be carried out, but no examples which disclose how to incorporate the instant claimed compounds into an oligonucleotide. Additionally, there are no examples which disclose how to make any of the requisite intermediate nucleoside and nucleotide-precursor compounds numbered "9," "10," "11" and "12" in the disclosure at pp. 12-13. For these reasons the exemplifications included within instant claims

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26-47 are deemed to represent subject matter which would require undue experimentation by the ordinary practitioner to determine how to make said compounds, and that therefore said claims lack adequate enabling support within the instant disclosure.

5 Applicant's arguments with respect to claim(s) 26-43 have been considered but are moot in view of the new grounds of rejection.

References made of record but not cited above are deemed to be either equivalents to the cited references or to be of interest as closely related prior art which shows the state of the relevant prior art.

10 Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines now operated by Group 1600 are (703) 308-4556 and (703) 305-3592 for Official documents. Before transmission of any Draft communications, Applicant is respectfully requested to seek instructions from instant Examiner.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

25 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor can be reached at (703)-308-1235.

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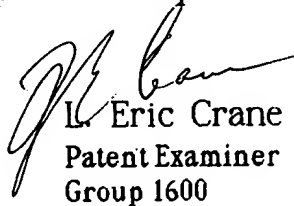
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Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235 .

LECrane:lec

5 10/7/99


L. Eric Crane
Patent Examiner
Group 1600